510(K) SUMMARY

SUMMARY STATEMENT – Revised Oct/2011

Trade Name: Therasage™ Heating Pad

Sponsor:
Therasage, L.L.C.
21000 Boca Rio Road
Suite A-21-C
Boca Raton, Florida 33433
Fax: 888-416-9991

Contact Name: Mr. Robert Besner (888-416-4441)

Device Generic Name: Electric-Powered Heating Pad with Infrared Heat

Classification: CFR 890.5500 Class II

Product Code: ILY

Product Description:

The Therasage™ Heating Pad provides infrared heat to different areas of the consumer's body. The Pad consists of an outer application cover enhanced with precious stones. The Pad's cover is fabricated of faux leather and a standard polyfiber fabric blend.

Indications for Use:

The Therasage™ Heating Pad is intended to provide topical heating to the user indicated for (a) the temporary relief of minor muscle and joint pain and stiffness; (b) the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains, and sprains, and minor muscular back pain; (c) muscular relaxation; and (d) the temporary increase of local circulation where applied.

Predicate Devices:

The Therasage™ Heating Pad is substantially similar to the: Thermotex Heat Therapy Systems (K092589), as well as the BIO-MAT 2000 (K072534) - Rich Way International Inc.

Technological Characteristics

The Therasage™ Heating Pad is an electrically-powered heating pad that generates infrared heat to affected body areas, providing temporary relief of minor muscle and joint pain.

The user can control the Pad's heat and temperature to the body by means of a 3-position switch. The manufacturer has evaluated the Pad's performance during laboratory bench testing to demonstrate infrared capability and its safety.

Summary of Technological Characteristics Compared to Predicate Devices

Similarly presented as its predicate devices, Therasage™ Heating Pad continues the same technological characteristics as its predecessors. As the following chart indicates, the function, design, and component definition are all basically the same.

TECHNOLOGICAL CHARACTERISTICS

CHARACTERISTICS	THERASAGE HEATING PAD	RICHWAY INTERNATIONAL BIO-MAT 2000 (obtained from labeling information)	THERMOTEX THERAPY HEAT SYSTEM (obtained from labeling information)	OTHER NOTES
FUNCTION	Distributes far infrared heat to user	Distributes far infrared heat to user	Distributes far infrared heat to user	
DESIGN	Small blanket design with jade stones on one side	Blanket or mat design with amethyst crystals on one side	Outer application cover with adjustable pads	See Note 3
Intended for over the counter use and not prescription use	Yes	Yes	Yes	
contains components derived from a biologic source	No	No	No	
Is device provided sterile?	No	No	No	
Is device intended for single use?	No	No	No	
Is device a reprocessed single use device?	No	No	No	
does device contain a drug?	No	No	No	

does device contain a biologic?	No	No	No	
does device use software?	Yes	Yes	Yes	
Is device implanted?	No	No	No	
MATERIAL	Primarily polyurethane (exterior) and cotton padding (interior)	Silk-cotton blend (17 layers of material)	Nylon-cotton blend	
ELECTRICAL SAFETY	Electrical Safety Testing Based upon standards of IEC60601-1 IEC 60601-1-2	Undisclosed	Undisclosed	See Note 4
POWER SOURCE	Electrical Current, 100-120v, 5 amps, 45-480 w. 50/60 Hz	Electric Current, 100-120v, 5 amps, 50/60 Hz 100-330 watts	Electric Current, 100-120v, 8-35 watts	
WHERE USED	Home, Office, or similar locations	Home, Office, or similar locations	Home, Office, or similar locations	

INTERFACE	See Note 1 Below	See Note 1 Below	See Note 1 Below	
ENERGY DELIVERED	35 ±°C to 60.5 ±°C	35 °C to 70°C	40° C - 45°C	
STANDARDS MET	ISO 14971 IEC 60601-1 IEC 60601-1-2 ISO 10993/G95-1 ISO 10993-18	Undisclosed	Undisclosed	Note 4
FDA PRODUCT CODE	ILY	ILY	ILY	
TARGET POPULATIONS	Persons over 10; persons who are not infants, invalids, unconscious, sleeping, or with poor circulation.	Persons who are not infants, invalid, unconscious, sleeping, or those with poor circulation.	Persons who are not infants, invalid, unconscious, sleeping, or those with poor circulation.	

ANATOMICAL USAGE	Any exterior locations where the application of heat would be helpful	Any exterior locations where the application of heat would be helpful	Any exterior locations where the application of heat would be helpful	
BIOCOMPATIBILITY	Testing through NAMSA completed pursuant to ISO 10993-18	Note 2	Laboratory bench testing and animal testing performed to demonstrate "infrared radiation capability and safety" (See, 510 K Summary)	See Note 3
STERILITIY	None (external use only)	None (external use only)	None (external use only)	
COMPATIBIITY WITH ENVIRONMENT	Fully compatible with an inside environment	Fully compatible with an inside environment	Fully compatible with an inside environment	
DURATION OF USE	Personal preference	Personal preference	30-45 minute recommended treatment time	
MAX TEMPERATURE ON THE SKIN	41°C	Undisclosed	Undisclosed	

MAXIMUM TIME SETTING	6 hours	Undisclosed	Undisclosed	
TIME SETTING INTERVALS	15 minutes	minutes	minutes	
SIZES	14" x 20" (small) 21" x 30" (med) 24" x 70" (large) 72" x 70" (prof.)	27.5" x 74"(prof) 32" x 20" (mini) Single, King, and Queen Sizes	Varies based on model and treatment modality	
METHOD OF GENERATING FIR HEAT	Electrical wiring and heating element	Undisclosed	Undisclosed	
SAFETY FEATURES	Auto shut-off on timer; heat sensor for potential over-heating; surge protector built into device	Auto time shut off feature	Safety Certifications from CSA-USA, CE, and UL (See Appendix B)	See Note 3

Note 1: Device User interfaces with device to set time and temperature for application; LCD Controller Screen shows temperature and time setting, power, and fault detection.

Note 2: The biocompatibility tests performed on the predicate devices, and their results, are not in the public domain. UL testing, however, was performed, to test successfully function, performance, safety and durability.

Note 3 Any differences in appearance or structure between the subject device and the predicate devices do not raise new questions of safety and effectiveness.

Note 4 In order to obtain premarket approval, the predicate devices were required to successfully pass the then applicable electrical safety standards. The subject device has similarly satisfied the most current safety standards recognized today.

Performance Data

In all instances, the Therasage Heating Pad functioned as intended and passed all manufacturing tests, including tests for functionability, performance, safety, and durability. These tests included routine evaluations during manufacturing and conformance to established standards. The results of these nonclinical tests which reflect substantial equivalence with the performance of the two cited predicate devices arise from testing for:

Relative Emissivity and Energy Density
Flammability
Electromagnetic Compatibility
Product Risk Evaluation
General Electrical Safety

In sum, the information from all of these tests and evaluations indicates without exception that the technology of the subject device and the predicate devices is substantially equivalent. Any technological, aesthetic, or ancillary differences between the Therasage Heating Pad and the predicate devices do not raise any questions of safety or effectiveness.

Substantial Equivalence

The subject device, as well as the indications for use and the technology upon which the device operates, is outlined above. It is a device that is substantially similar to at least two predicate devices. Such substantial equivalence presents the subject device as being as safe and effective as the predicate devices. The Therasage Heating Pad has the same intended uses and similar indications as the predicate devices. The technological differences, if any, between the Therasage Heating Pad and the predicate devices are insubstantial and are aesthetic differences, at best. No discerned technological differences exist that raise, suggest, or implicate any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Therasage, LLC
% Underwriters Laboratories, Incorporated
Mr. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

MAR - 6 2012

Re: K120254
Trade/Device Name: Therasage™ Heating Pad
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY, IRT
Dated: January 25, 2012
Received: January 27, 2012

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 4.1

Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: Therasage™ Heating Pad

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use XX (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120254